SAFETY NEEDLE ASSEMBLY AND METHOD FOR MAKING THE SAME

Cross Reference to Related Applications

[001] The instant invention is related to the invention disclosed in the application entitled "Needle Protection Assembly" (Attorney docket No. 0100/0149) filed on August 27, 2003. The disclosure of the related application is incorporated by reference to this application.

Field of the Invention

[002] The present invention relates to needles and more particularly a safety needle assembly in which the needle sheath for protecting the needle prior to use is attached to a collar rotatably mounted about the needle hub of the needle assembly.

Background of the Invention

[003] There are a number of needle protection devices disclosed in the prior art. Among them are a number of patents assigned to the same assignee as the instant invention. Without limitations, some of those patents are: 4,982,842; 5,139,489; 5,154,285; 5,232,454; 5,277,311; 5,993,426; 6,328,713; 6,334,857; RE37,110 and RE37,252. Some other patents that describe needle protection devices, or parts thereof, include U.S. patents: 4,664,259; 5,037,401; 5,171,303; 5,188,611; 5,490,841; 5,509,907; 5,584,816; 5,599,313; 5,599,318; 5,632,732; 5,643,219; 5,662,617; 5,665,075; 5,669,889; 5,681,295; 5,697,908; 5,733,265; 5,868,716; 5,891,103; 5,913,846; 5,919,165 and 6,440,104.

[004] The needle protection assembly of the instant invention is made up of parts that are radically different from the prior art, as exemplified by the above-noted patents.

Summary of the Present Invention

[005] The safety needle assembly of the instant invention is designed to enable a user to connect the needle hub to a medical device, such as for example a syringe, by grasping the needle hub proper, thereby ensuring a more secure fit to the syringe. Unlike the prior art needle assemblies, the sheath that covers the needle plays no part in the securing of the needle hub to the medical device.

[006] The needle hub is especially designed to have a ring surrounding the luer end of the hub to allow a user to grasp this ring to couple the needle hub to the medical device. The ring is an integral part of the needle hub and it has a distal wall that extends orthogonally from a proximal portion of the main body of the hub, with the body of the ring extending rearward to cover the luer end of the needle hub that couples to a corresponding luer of the medical device. The circumferential side wall of the ring is spaced from the luer of the needle hub . The proximal end of the ring is open to allow the mating of the luer of the needle hub to the corresponding luer of the medical device. To enable the user to see the initial blood flash so as to determine whether the needle has correctly been inserted into the vein of a patient during blood drawing, windows are provided at the sidewall of the ring to allow the user to have a clear view of the luer body, and the luer end.

[007] The needle hub has at its distal portion a number of flanges formed along a circumferential axis. The flanges are chamfered at their respective surfaces that face the needle extending from the distal end of the needle hub. The back surfaces of the flanges are flat for defining a space between the flanges and the distal wall of the ring circumferentially formed about the distal portion of the needle hub.

[008] A collar to which a needle protection housing is attached is fitted to the space defined by the flanges and the distal wall of the ring on the needle hub. To facilitate

the fitting, a number of internal protrusions or bosses are provided at the proximal end of the collar. The respective surfaces of the protrusions that come into contact with the flanges at the needle hub are also chamfered to facilitate the mating of the collar to the needle hub. The back end of the substantially rectangular protrusions are flat, so that once the collar is fitted to the needle hub, it could not be removed therefrom.

[009] At the distal portion of the collar there is formed a circumferential internal rib. Slots are also provided at the distal portion of the collar to enable the flexing of the distal end of the collar for the insertion and removal of a needle sheath that removably couples thereto.

[0010] The collar has pivotally or hingedly attached thereto a housing which is pivotable to the direction along a longitudinal axis of the needle hub for covering the needle after use. Formed substantially along the length of the housing is an opening that is off centered. The opening is formed by two lips or flaps that extend substantially along the length of the housing, with the first or upper lip overlapping the second or lower lip. The respective lips each are angled toward the interior of the housing, but with varying angles along the lengths of the lips. As a consequence, when the housing is pivoted to cover a used or contaminated needle, the needle would enter into the housing guided by the lips at angles that ensure that it smoothly enters into the housing, thereby preventing flickering of any contaminated fluid that may have adhered to the needle. The lips, particularly the lower lip, are designed such that, once fully enters into the housing, the needle is prevented from escaping from the housing. For added safety, respective portions of a locking mechanism are provided at the base portion of the housing and the outer surface of the distal portion of the collar.

[0011] The needle sheath that covers the needle prior to use has a notch or groove formed circumferentially proximate to its open end. During manufacturing of the needle assembly, the needle sheath is placed or positioned over the needle and moved along the longitudinal axis of the device to mate with the distal portion of the collar mounted about the needle hub. With a predetermined force, the needle sheath is coupled to the collar, with the rib at the distal end of the collar fitting into the groove formed at the proximal end of the needle sheath.

[0012] To remove the safety needle assembly of the instant invention from the medical device, the user would grasp the ring of the needle hub and rotate the needle assembly in a rotational movement that is counter to the rotational movement used to couple the needle assembly to the medical device, if the coupling of the needle assembly to the medical device is via luer lock coupling. If it is a luer fit coupling, then the user would pull the needle assembly away from the medical device.

Brief Description of the Figures

[0013] The present invention will become apparent and the invention itself will be best understood with reference to the following description of an embodiment of the present invention taken in conjunction with the accompanying drawings, wherein:

[0014] Fig. 1 is a perspective view showing the different component parts of the safety needle assembly of the instant invention;

[0015] Fig. 2 is a perspective view showing the various components of the safety needle assembly of Fig. 1 and a medical device such as a conventional needle syringe to which the safety needle assembly of the instant invention is used with;

[0016] Fig. 3 is a perspective view of the safety needle assembly of the instant invention with all of the components assembled;

[0017] Fig. 4 is a cross-sectional view of the safety needle assembly of the instant invention;

[0018] Fig. 5 is a perspective cross-sectional view of the needle assembly of the instant invention;

[0019] Fig. 6 is a perspective view of the needle hub of the safety needle assembly of the instant invention as viewed from its proximal end;

[0020] Fig. 7 is a perspective view of the needle hub of the instant invention safety needle assembly viewed from its distal end;

[0021] Fig. 8 is a perspective view of the needle protection housing and the collar to which it is attached;

[0022] Fig. 9 is another perspective view of the Fig. 8 needle protection housing and collar;

[0023] Fig. 10 is yet another view of the needle protection housing and collar of the instant invention safety needle assembly, with the lips that form the longitudinal slot along the housing clearly shown;

[0024] Fig. 11 is a plan view of the needle protection housing and the collar component of the safety needle assembly of the instant invention;

[0025] Fig. 12 is a perspective view of the needle sheath of the instant invention safety needle assembly as viewed from its open end; and

[0026] Fig. 13 is another perspective view of the needle sheath of Fig. 12 but viewed from its closed end.

Detailed Description of the Invention

[0027] With reference to Fig. 1, the safety needle assembly 2 of the instant invention is shown to comprise four major components, namely a needle hub 4, a collar 6, a needle protection housing 8 attached to the collar 6 via a living hinge 10, and a needle sheath 12. As shown, needle hub 4, collar 6 and needle sheath 12 are in alignment along a longitudinal axis 14. The exposed components of the safety needle assembly of the instant invention are further shown in Fig. 2 to be in alignment with a conventional syringe 16 with a luer lock receptacle end that mates with needle hub 4. An assembled safety needle assembly of the instant invention is shown in perspective view in Fig. 3 and in cross-sectional views in Figs. 4 and 5.

[0028] With reference to Figs. 1-5 and further with reference to Figs. 6 and 7, needle hub 4 is shown to have a proximal portion 18 and a distal portion 20. For the sake of clarity, a needle 22 that fixedly extends from extension 24 of needle hub 4 is not shown in Figs. 6 and 7. Further, it should be appreciated that proximal portion 18 and distal portion 20 of needle hub 4 do not have any actual line of demarcation, and are shown as such in Figs. 4, 6 and 7 solely for the convenience of the reader.

[0029] As best shown in Fig. 6 and the cross-sectional views of Figs. 4 and 5, needle hub 4 comprises a main body portion 26 that includes the base of needle hub 4. A ring 28 circumferentially surrounds the proximal portion of needle hub 4 in spaced relationship to main body portion 26. As shown, ring 28 is a part of needle

hub 4 and is an integral part of main body portion 26 by means of a distal wall or partition 30 that extends transversely or orthogonally from main body portion 26. From distal wall 30 the sidewall 32 of collar 28 extends to a proximal end 34 that has an opening 36 formed concentrically with opening or cavity 38 at luer end 40 of needle hub main body portion 26. Since sidewall 32 of ring 28 is in spaced relationship with main body portion or base 26 of needle hub 4, luer end 40 of needle hub 4 accordingly is threadingly matable with a corresponding luer connector such as that shown for syringe 16 in Fig. 2.

[0030] Ring 28 is also provided with two openings or windows 42 along its sidewall 32 to enable a user to view base portion 26 of needle hub 4. As needle hub 4, and the other components of the needle assembly, are made of conventional medical plastic such as polypropylene, or ABS plastic, and is substantially clear except for a color tinting as a way of color coding the assembly, the user can readily ascertain any flashing or blood, or blood flash, during a blood withdrawing procedure to thereby determine whether needle 22 has been correctly inserted into the vein of a patient. Thus, by way of windows 42, a user can view the base portion, as well as luer end 40 of needle hub 4. The dimension of ring 28 is such that it enables the user to readily grasp needle hub 4, and therefore the safety needle assembly as shown in Fig. 3, for mating to syringe 16 as shown in Fig. 2. As is well known, luer end 40 of needle hub 4 may be coupled to the corresponding luer end 44 of syringe 16 by a rotational movement when syringe 16 has a luer lock type receptacle, as shown in Fig. 2. Alternatively, in the case where the syringe has a luer slip type receptacle, the user, upon grasping ring 28, can simply insert luer 40 onto the luer slip receptacle of the syringe.

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IT SHOULD OF COURSE BE APPRECIATED THAT THE SAFETY NEEDLE ASSEMBLY OF THE INSTANT INVENTION CAN ALSO BE USED FOR INFUSION PROCEDURES.

[0031] Further with respect to Figs. 1-7 and in particular with respect to Figs. 6 and 7, at the distal portion 20 of needle hub 4 there are provided a number of flanges 44

in a coaxially circumferential manner a predetermine distance from end wall 30 of ring 28. Flanges 44 each are chamfered or beveled at its front surface 46, and extend circumferentially proximate to the front end of cavity 38 of the base portion 26 of needle hub 4. As best shown in Figs. 4 and 5, cavity 38 of base portion 26 is connected to needle 22 by a through bore 50 at extension 24. Extension 24 has a number of elongated ribs 56, which has no bearing for this invention other than for cosmetic and manufacturing processes not related to the instant invention, as ribs 56 do not come into contact with needle sheath 12 at any time. With flanges 44 extending from base portion 26 a predetermined distance from end wall 30, a space 52 is defined between flanges 44 and end wall 30 circumferentially about base portion 26. As best shown in Fig. 6, the back surfaces 54 of flanges 44 are formed at right angle to base portion 26.

[0032] As shown in Figs. 1-5, needle hub 4 is in alignment with collar 6 and is coupled thereto per shown in the assembled views of Figs. 3-5. In particular, with reference to Figs. 8-11, collar 6 is pivotally connected to needle protection housing 8 by living hinge 10. As shown in Fig. 1, housing 8 is pivotable in the direction indicated by directional arrow 56, i.e., toward the longitudinal axis 14 for covering needle 22.

[0033] Collar 6 is cylindrical in shape and has a proximal portion or end 58 and a distal portion or end 60. There are formed at the inner surface at proximal portion 58 of collar 6 a plurality of protrusions 62 which are substantially rectangularly shaped. Protrusions 62 each may have a chamfered surface 64 that faces needle hub 4, as shown in the alignment of the components illustration of Fig. 1. Moreover, protrusion 62 are dimensioned such that when collar 6 is press-fitted to needle hub 4, they will matingly fit to space 52 defined by flanges 54 and end wall 30 at the distal portion of needle 4. The respective dimensions of space 52 and protrusions

62 may be such that, although collar 6 is rotatable about base portion 26 of needle hub 4, there nonetheless is enough friction between either one of flanges 44, end wall 30 or the outer surface of needle hub base 26 and protrusions 62 to render collar 6 not freely rotatable about needle 4, unless a predetermined torque or force is applied either to needle protection housing 8, living hinge 10 or collar 6, to rotate collar 6 relative to needle hub 4. Voids 66 provided at proximal portion 58 of collar 6 enable proximal portion 58 to flex, or expand, when collar 6 is press-fitted to the distal portion of needle hub 4, particularly when protrusions 62 come into contact with flanges 44. The respective chamfered or beveled surfaces 46 and 64 of flanges 44 and protrusions 62, respectively, facilitate the insertion of collar 6, and more particularly protrusions 62 into space 52 of needle hub 4.

[0034] Distal portion 60 of collar 6 has at its distal end, or proximate thereto, a rib 68 formed at the inner surface of collar 6. For the embodiment shown, rib 68 is divided into two halves, per notches 70 formed at opposed sides of distal portion 60. Notches 70 provide additional flexibility to the distal portion of collar 6 when needle sheath 12 is fitted thereto. More on that later. For now, it should be appreciated that rib 68 is formed to have either a semi-circular configuration or a configuration that is made up of a number of beveled surfaces for facilitating the mating of distal portion 60 of collar 6 with the proximal portion 74 of needle sheath 12. The beveled surfaces of rib 68 are collectively designated 72.

[0035] Needle protection housing 8 is connected, by living hinge 10, to collar 6 at the latter's proximal portion 58. Needle protective housing 8 has an open proximal end 75 and a closed end 78. Housing 8 is cylindrical in shape and has an opening 80 through which needle 22 passes, when housing 8 is pivoted toward collar 6 for covering needle 22 after needle sheath 12 has been removed from collar 6. Opening or channel 80 is formed by two lips or flaps 82 and 84 each of which

extends longitudinally along the entire length of housing 8. Lip 82 overlaps lip 84, with the overlapping being such that the combination of lips 82 and 84 providing a trap door for needle 22. Thus, once needle 22 passes lips 82 and 84 into housing 8, it is trapped within housing 8 and is prevented from being further exposed.

[0036] Opening 80, due to its formation by lips 82 and 84, is off-centered to one side of housing 8 to enhance the entry of needle 22 into housing 8. Each of lips 82 and 84 is angled, by a series of complex angles, as best shown in Figs. 10 and 11, toward the interior of housing 8. The respective angles of each of the lips are therefore varied along the length of the housing for guiding needle 22 into housing 8 via opening 80. The respective progressively angled surfaces of lips 82 and 84 are designated 86 and 88, respectively. Given that the entry of needle 22 into housing 8 is guided by lips 82 and 84, the angled entry of needle 22 into housing 8 is effected in a smooth manner to substantially eliminate the possibility that contaminated fluid that remains on needle 22 after its use may be flickered or splattered when needle 22 comes into contact with housing 8.

[0037] To ensure that needle protection housing 8 remains fixedly retained along the longitudinal axis 14, a lock mechanism is provided at the proximal end 75 of needle housing 8 and the outer surface of collar 6. This ensures that once needle housing 8 is pivoted to the position along longitudinal axis 14, it will remain in alignment thereat. This lock mechanism, as shown in Figs. 1-3 and 9-11, comprises two apertures 76 at the base of needle housing 8, and two corresponding one-way downward sloping catch members 74 at collar 6. Alternatively, as should readily be recognized, the apertures and catch members may be formed at collar 6 and the base of housing 8, respectively. Further, instead of apertures, non-through openings that nonetheless mate to the catch members are also envisioned. When needle protection housing 8 is pivoted to be in alignment along longitudinal axis 14, aperture

76 will snap fit over the one-way catch members 74, with the base surfaces 73 of the one-way catch members 74 acting against the top surfaces 77 at the base of apertures 76 to thereby fixedly retain needle housing 8 relative to collar 6.

[0038] As shown in Figs. 12 and 13, needle sheath 12 has a first engage mechanism that engages to a second engage mechanism at collar 6. In particular, needle sheath 12 is a cylindrical cap that has formed at its proximal portion 74 a circumferential groove or slot 90. Groove 90 is configured to have a dimension, as defined by stop 92 and proximal portion 74, to accept rib 68 of collar 6. As shown, proximal portion 74 of needle sheath 12 has an opening 94 that allows needle sheath 12 to be placed or positioned over needle 22 and be press-fitted onto the distal end of collar 6. As the distal end of collar 6 has a rib 68 and opposed slots 70, when needle sheath 12 is fitted to collar 6, due to the elastic properties of the plastic material from which both collar 6 and needle sheath 12 are molded, the distal end of collar 6 would expand slightly so as to accept the proximal portion 74 of needle sheath 12, until rib 68 is snap fitted into groove 90, and the edge of the distal end of collar 6 rests against stop 92. Once snap fitted to collar 6, needle sheath 12 is removably engaged to collar 6. To remove needle sheath 12 from collar 6, a predetermined or greater force is applied to needle sheath 12 along longitudinal axis 14 for separating needle sheath 12 from collar 6. As best shown in Fig. 13, needle sheath 12 has a closed distal end 96.

[0039] In operation, with the assembled safety needle assembly as shown in Fig. 3, a user would remove needle sheath 12 by applying a predetermined force longitudinally relative to collar 6. Once exposed, needle 22 may be used. After use, needle protective housing 8 is pivoted to be in substantial alignment along longitudinal axis 14 so that the contaminated needle 22 enters into housing 8 and is trapped inside housing 8 by the trapdoor formed by lips 82 and 84. At the same

time, housing 8 is fixedly retained to collar 6 by the mating of apertures 76 at the base of housing 8 to the one-way catch member 74 at the outer surface of collar 6. To remove needle hub 4 from the syringe, ring 28 of needle hub 4 is grasped, and in the case of a luer lock coupling, rotated counter-clockwise to remove needle hub 4 from the syringe, such as 16 shown in Fig. 2. Once removed from the syringe, the safety needle assembly could be properly disposed.